



# A Comprehensive Outline of the Gulf Nations' Cosmetics Review and Approval Process: GSO Standards

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## Authors' contributions

*This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.*

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## ABSTRACT

The GCC is an economic and political union of six countries: Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the UAE. The council's main office is in Riyadh, Saudi Arabia. To ensure that cosmetic products are safe, the Gulf Cooperation Council Standardization Organization (GSO) recently recommended GSO 1943: 2015, "Safe Cosmetics and Personal Care Products." The GCC Standardization Organization, a comparable agency, can develop standards that apply to everybody. The product must have entire pork and detachable flesh, be devoid of any unclean or rotting construction, and be safe for human and environmental health. Cosmetics are tightly controlled in GCC nations, following EU guidelines. Before items are utilized by customers, they must be registered and meet all safety criteria. This has led to the formation of GCC cosmetic standards. The Gulf Cooperation Council cosmetics legislation closely follows the EU Cosmetics Regulation 1223/2009. However, it has some of its own criteria when it comes to processes, ingredients, labelling and claims.

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## 1. INTRODUCTION

Cosmetics are defined as “any substance or mixture intended to be attached to the outside portions of the human physique (epidermis, hair system, nails, lips, and external genitals), to the fangs and self-lubricating membranes of the mouth only” [1]. Products should fulfil certain requirements, some of which are: they should be completely free from pork and its derivatives, they should be safe for human health under normal and reasonably foreseeable conditions of use, they should be stable and their properties impacting safety, efficacy and quality should not change during their shelf life, they should be free from any filthy or decomposed substances.

The concept of a beauty product is similar to that of a cosmetic product, and safety standards include:

1. The product should include no pork or pork components.
2. It should be safe to use under typical or expected conditions.
3. Its qualities should not alter over time when it is kept and utilised as directed.
4. It must be clean and devoid of decay.
5. It can't contain pictures, photographs, or statements that violate GCC Islamic customs or social values.
6. Conditions for use of cosmetics and personal care items are not satisfied.
7. Chemical tracking is authorised if it is technically unavoidable in acceptable performance.
8. Sunscreen goods must meet GSO 2237:2012

"Cosmetics-Sunscreen products" Cosmetics should be produced using good manufacturing practises. Good manufacturing practises are considered when production is carried out in accordance with applicable comparable standards, such as GSO ISO 22716. Cosmetics and personal care products must comply with GSO ISO 17516 "Microbiology-Microbiological Limitations." It should be between 4 and 8, except for those indicated in Annex 3 that are specific to certain objects. Manufacturing items with pH values not on this list will be approved if proof of pH is required to achieve desired performance and a safety report is supplied. A tiny quantity of inadvertently forbidden chemicals in excellent manufacturing performance is

permitted provided it meets safety requirements [1].

The Gulf Cooperation Council (GCC) is a political and economic alliance of Saudi Arabia, Kuwait, United Arab Emirates, Qatar, Bahrain and Oman. The countries in this alliance share a common body that is authorized to publish the standards applicable in all of the countries: the GCC Standardization Organization (GSO). Each country then has a separate local competent authority that is responsible for enforcing the common standards.

The overall regulatory framework governing cosmetics in the region was finalized and published in 2016. There are three pieces of legislation that cover cosmetic products, each dealing with a different part of the compliance criteria:

Safety: GSO 1943/2016: Safety Requirements of Cosmetics and Personal Care Products.

Claims: GSO 2528/2016: Cosmetic products – Technical Regulation of Cosmetic and Personal Care Product Claims.

GMP: GSO ISO 22716: Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices.

### 1.1 General Labeling Requirements

i. All cosmetics and personal care items must bear the following indelible, readable information:

- 1) Product name and logo
- 2) Name and address of manufacturer/distributor
- 3) Origin of the product
- 4) Nominal content
- 5) Labelling and labelling regulations for items that degrade within 30 months after manufacturing
- 6) The product's handbook contains usage instructions, warnings, and precautions.
- 7) Batch data
- 8) Product role

The primary container and its packing must be marked with this information. This information can also be placed on the box. The aforementioned information must be on the label of each cosmetic product's container and

packaging. All information required above must be in Arabic or English. This information must be stated in both Arabic and English on the goods.

- Brand name
- Use of the product instructions
- Warnings and precautions
- To keep your equipment, secure, you must follow the storage instructions.

iii. The following items require special labelling:

- Gift sets and kits that contain numerous cosmetics and personal care items but are not packaged.
- Hospitality
- Cosmetic and personal care multi-packs
- Ampule and vial-based cosmetics (should include the following instructions in Arabic and English)

#### Packing

1. Cosmetics and personal care items should be wrapped to prevent harm and fight on the ground when stored, transported, and handled as directed by the manufacturer.

2. Metal aerosol dispensers are found in cosmetics and personal care product packaging (GSO 917). [2].

1.2 Labelling must correspond to Islamic culture and societal norms; some label parts must be translated to Arabic; and such prerogatives must be honest. Except for Bahrain, where no product notice is needed. Customs clearance criteria vary by nation. Regardless, the GCC shares a basic rule [3].

## 2. MATERIALS AND METHODS

### 2.1 Cosmetics Registration – KUWAIT

Cosmetics are registered with the Department of Health Drug Administration and Food Control under Resolution 97/200. Products must fulfil the GCC's statutory GSO requirements to be registered. Kuwait is a GCC member [4].

#### Requirements

- In the member's official language, products must have adequate, explicit, and easily understood risk warnings (Arabic).
- The product or packaging must have the manufacturer's name, contact information, and

product reference. Alternatively, batch details can be shown if available.

This resolution prohibits the use of 1,4-Dioxane as an ingredient in cosmetics, cosmetics, and shampoo products [5].

General Import and Export Requirements for Cosmetic Products in Kuwait

1. Initial manufacturer or distributor appointment letter shall be known to Arab Chamber of Commerce and Kuwait Embassy.

2.1 The Free Trade Certificate (FSC) issued and formally certified by the competent cosmetic government official or the organisation responsible for the sale of cosmetic products in the country of origin, and the Kuwaiti Embassy in the country of origin.

3. A copy of the manufacturing licence, GMP or ISO certificate, and the Kuwait Embassy.

4. Detailed product description on firm letterhead, signed and stamped by the manufacturer.

5. A health certificate declaring that the items do not include BSE or any biological addiction from animals (elastin, collagen, ceramides, glycosaminoglycans; liver excretion; lung excretion; hypothalamus; bone marrow transplantation; sphingolipid; tonsil; etc.)

The items do not include corticosteroids, hormones, or other hazardous substances, and are suitable for human usage in regular situations.

7. Each shipment shall have a maximum of 7 days between manufacturing and expiry.

8. The manufacturer and country of origin should be printed in English or Arabic on the product packaging.

10. Samples of full reading and registration must be supplied to the department, as well as a letter from the agent's Kuwaiti letterhead. Submitted invoices must have a clear terminology, legible print, and be in English or Arabic, or require an accurate translation if not [6].

10. List the countries where the items are sold by date.

11. The release invoice should contain the following: (a) Name and address of Kuwaiti agent, with shipping address (b) The manufacturer's name, address, and country of origin.

#### Additional requirements [7]

A certificate from the state health authority stating that the product has no metabolic/endocrine action and does not contain pathogenic microorganisms or infectious

substances is required. The efficacy and safety of items from a company that claim to create changes in the body such as whitening, weight reduction, body sculpting and hair loss.

Certificate of manufacture specifying kind of strands used for cosmetic hair and body brushes, toothbrushes and loofas, as well as most brush names

## 2.2 Cosmetic Registration - SAUDI ARABIA [8,9]

The Saudi Food and Drug Authority (SFDA) devised this approach to assure high quality and safety of imported cosmetics.

Verification Process [10,11]

The importer must have an SFDA account.

Products must fulfil GSO technical regulation GSO 1943/2016.

Cosmeceuticals and perfumes must be registered and reported via the SFDA's "E-Cosma" Cosmetics Trade must be included on the Export Registration Certificate with the Importer.

Process Flow [12]

- The exporter/importer must complete and submit the RFC.
  - Upon receipt, the application is evaluated by a local consultant.
- Review all key papers to assess scope & needs.
- In compliance with SFDA rules, the consultant will arrange for appropriate verification (sample testing, testing, and/or auditing).
  - Please provide the latest eCosma figures from the SFDA E Cosma webpage.
  - If the results are satisfactory, Cotecna will provide a Certificate of Compliance.

SFDA-approved items are

- Anti-wrinkle items
- Bath and shower fixtures (salt, foam, oil, gels, etc.)
- Skin oils and creams (hands, face, feet, etc.).
- Refining areas
- Facial masks (excluding scratch products)
- Bulk cosmetic goods
- Make powders, after washing powder, clean powder, etc.
- Fragrances, toilet water
- Makeup builder and remover for face and eyes
- Nail care and cosmetics
- Sunscreens

- Oral products
- Razors
- Sunscreens
- Toilets, perfumed soaps, glycerine soap, etc.

## 2.3 Cosmetic Registration – UAE [13]

Cosmetics must be registered with Dubai Municipality (DM) and Emirates Authority for Standardization & Metrology (EASM) (EASM). DM registration allows for multiple sales, whereas ESMA registration allows for one entry. An UAE firm must hold a "wholesale" licence to register items. So, registration requires a local representative.

## 2.4 Cosmetics Registration – QATAR [14]

- Fill out the form with the required information and double check that all the documents in the "Required Documents"
- After completing the application form, attach the documents listed in the required documentation section.
- Double-check the application form before submitting it to the appropriate MOPH department at the pharmacy and drug control department. The address can be found in the "Office Locations and Contacts" section of the website.
- The authorities will review the application and verify the documents submitted.
- Pharmaceutical items, dietary supplements, and medical cosmetics companies will be registered following the verification process.
  - a copy of the applicant's Qatari identity document.
  - Copies of commercial license.
  - a copy of the business registration [15].

### Step 1:

- A copy of the Department of Medical Licensing Registration Certificate in pharmaceutical companies, industries, and retailers.
- The first agency agreement confirmed by the Qatar Department of Foreign Affairs.
- The first Good Production Certificate (GMP) issued by a government official in the country of origin, or a copy approved by the Qatari Ministry of Foreign Affairs if it is not available.
- Original or equivalent production license

certificate from the original country, approved by the Qatari Ministry of Foreign Affairs, or a copy approved by the Qatari Ministry of Foreign Affairs if it is not available.

- List of products available for purchase in the country of origin.
- Copy of manufacturer's registration certificates in GCC countries with reference laboratories.
- A copy of the Department of Drug and Drug Administration license.
- A list of countries where the company's assets were available for purchase.
- Original affiliate letter from the manufacturing company details of the products that the company has distributed [16].

**Step 2:**

- The authority of the nation of origin originates the certificate of free trade (original and certified by the Ministry of Foreign Affairs, Qatar).
- Certified structured and certified certificate See section four.
- Certificate of analysis (original and verified)
- CIF certificate value (original and verified).
- Copy of the product label and brochure used in the country of imported goods.
- Copy of product registration or any other product or product (product) registered on

any GCC reference in the manufacturer's country.

- A copy of the reference in support of your claim (if any).
- Analysis method, and any methods that may be required by the Drug Lab.
- Six product samples must be submitted.
- For indoor and outdoor packaging of food ingredients used in sports, there should be an English and / or Arabic label stating "Product licensing does not guarantee that the product is free of contraindications and the athlete is using the ingredients and his or her risk of drug testing."
- Certificate of hormone-free, anabolic steroid-free, anti-inflammatory steroid-free, psychotropic-drug-free, alcohol-free, product heavy-free product Pig - byproducts of pathogenic germs and fungus.

**Step 3:**

The information must be in Arabic and / or English and include the following:

- Name or brand name.
- Product name (if available).
- Medication dosage form.
- Package size.
- List of active ingredients (name of herbs should be scientifically written).

SUPPORTING DOCUMENTS	REMARKS
a. Copy of registration certificate of pharmaceutical companies' factories & brokers from medical licensing dept	
b. Agency Agreement	
c. GMP	
d. Company license certificate at Country of origin	
e. A list of products on sale in country of origin	
f. Copy of Company registration at GCC Reference Counters	
g. A copy of licensed store issued by pharmacy & drug control dept	
h. A list of countries in which company product were on sale	
i. Filled form A	
j. An original relationship letter if the Mfg. company is different from theDist company	

**Fig. 1. Documents required for a Company Registration in Qatar [17]**

SUPPORTING DOCUMENTS	REMARKS
1. Registration certificate (blue form + form B)	
2. Registration certificate at GCC Ref. Countries	
3. Free sale certificate	
4. Composition certificate	
5. Certificate of analysis	
6. Product label and leaflet in the country of origin	
7. Price list	
8. Certificate of free of the product from hormones, anabolic steroids, anti-inflammatory steroids, psychotropic drugs, alcohol, heavy metals, pathogenic bacteria and fungi, pork & pork – derivatives <b>if are not included in the certificate of analysis</b>	

**Fig. 2. Documents required for a product registration in Qatar [17]**

### 2.5 Cosmetic Registration – OMAN [18]

1. Cosmetics and personal care goods supplied in Oman must fulfil Sultanate health and safety regulations (GSS). The Department of Trade and Industry said the decision to utilise standard GSS data was taken in compliance with Royal Decree 11/2017.
2. As stated in Article 1, "Safety measures for cosmetics and self-care items will include GCC information as an Omani norm." To be covered in this decision are any cosmetics and personal care items sold in Oman or utilised in Oman. "Violators shall be fined no more than RO 1,000, which is enhanced if a repeat violation occurs, as per Article 2 [19].
3. Members of the GCC's National Standards Bodies make up the GSO. The GSO standard covers any device or chemical designed to connect with the human body's exterior organs. In addition to cleaning, perfume creating, adjusting its entry, shielding, keeping them in good health or dealing with body scent are covered in the standard.
4. The GCC's cosmetics law is fairly comparable to the EU's. But it has its own regulations for techniques, ingredients, labelling, and claims. The items must not

contain the pig or its products, must not violate religious or societal values, and must not jeopardise public morals. Stable structural components that impact safety, efficiency, and quality must not alter at the same time. In addition to adhering to Islamic culture and cultural conventions, certain label components must be translated into Arabic [20].

5. Topical medications that cure or prevent illness, or other active compounds that modify the human body's structure or function, are classed as such.
6. An item indicated in Annex (4) must be present in high density in any product.
7. Medical remedies for illnesses like diabetes and nappy rash are also classified as health goods. [21,10]

### 2.6 Cosmetic Registration – BAHRAIN [22,23]

#### Requirements

1. For a special agency in Bahrain, the first letter of appointment was stamped and signed by the manufacturer or distributor.
2. Copy of Commercial Registration
3. The manufacturer's name, place of origin, and product names are all listed on the cosmetic product license application form.

4. A public health authority has issued and prepared a Good Production Certificate.
5. Free Sale Certificate, which includes the name, address, and name of the products to be imported, and issued and prepared by the national health authorities and the Bahrain Embassy in the country of origin.
6. The design certificate for each product, stamped and certified by the manufacturer, indicates the percentage of the item and its purpose.
7. Certificate of analysis from a recognized product laboratory
8. If the product contains active ingredients or claims that cause changes in the body, documentation and medical studies should be included to prove its effectiveness, safety, toxicity profile, side effects, study stability, duration, duration, packaging quality, and analysis method as required.
9. Samples of the product in its original (non-returnable) packaging with an external and / or internal label or insert a leaflet containing basic English and Arabic details
10. The product is certified to be free of pneumonia
11. Halal Certificate
12. Scientific references to herbal safety, legitimacy, use and effectiveness are required if the product contains.
13. If the product contains active ingredients or claims, the following information is required: [24]
  - Performance
  - Safety check
  - Toxic profile of ingredients
  - Unpleasant side effects
  - Strength research
  - Working time, storage conditions and type of packaging
  - Analysis method

## 4. RESULTS

### 4.1 GCC Technical Regulation for Cosmetic Products [18,19]

The Gulf Cooperation Council Standardization Organization (GSO) recently proposed a draft GCC Technical Regulation GSO 1943:2015 "Cosmetic Products -Safety Requirements of Cosmetics and Personal Care Products," which specifies the definitions of the product, safety requirements, labelling, product claims, packaging and rules for acceptance and rejection. Safety Requirements Cosmetic and

personal care products shall fulfill the following requirements:

1. The product shall be completely free from pork and all its derivatives.
2. It shall be safe for human health when used under normal or reasonably foreseeable conditions of use.
3. It shall be homogenous, stable and the properties shall not change during its shelf life when stored and used as per the instructions.
4. It shall be free from any filthy or decomposed substance.
5. It shall not contain graphics or images or phrases that are inconsistent with Islamic traditions and prevailing social values in GCC countries.
6. Cosmetic and personal care products shall not contain substances listed in the annexes with conditions.
7. The presence of traces of the substances listed in annex 2 shall be allowed provided that such presence is technically unavoidable in good manufacturing practice.
8. Sunscreen products shall comply with the articles 5.11 and 9.9 in GSO 2237:2012 "Cosmetics Sunscreen products."
9. The manufacture of cosmetic products shall comply with good manufacturing practices. Compliance with good manufacturing practices shall be presumed where the manufacture is in accordance with the relevant harmonized standards such as GSO ISO 22716.
10. Cosmetics and personal care products shall comply with the microbiological limits in GSO ISO.
11. The pH of cosmetic products should be in the range (4-8) excluding the ranges in Annex 3 that are specific to certain ingredients. Certain products formulated with pH values outside this range shall be acceptable if they have evidence to demonstrate that the pH is necessary to achieve the required efficacy and also have a demonstrable safety report.
12. The non-intended presence of small quantity of a prohibited substance, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with point 2.

In the case of its presence as an impurity, cosmetic and personal care products should not exceed the following limits:

Substance	Lead	Arsenic	Cadmium	Mercury	Antimony	Dioxane
Limits	10 ppm	3 ppm	3 ppm	3 ppm	5 ppm	10 ppm

## 5. LABELING REQUIREMENTS

1. All cosmetic and personal care products shall bear the following information in indelible, easily legible and visible lettering:
  - a. The name of the product and the name of trademark
  - b. The name and address of manufacturer or distributor
  - c. Country of origin of the product
  - d. Nominal content of the product
  - e. The time period labelling and marking requirements for product deteriorating within and after 30 months from the date of manufacturing
  - f. Conditions of use, warning statements and precautionary information
  - g. Batch number or lot code
  - h. Product function
  - i. List of Ingredients shall be printed on either both primary container and packaging or only packaging of the product or tag, cards
1. The information required by items 1) to 8) above must appear on the label of both the container and the packaging of each individual cosmetic product.
2. The information required by items 1) to 5) above shall be at least in Arabic or English. However the following information must be presented in both Arabic and English on the products:

- Name of the product
  - Product function and/or use instructions
  - Warnings instructions and precautionary information
  - Necessary storage instructions for safe use
4. There are specific labelling requirements for the following products:
- Toilet soap that are supplied neither in a container or packaging
  - Gift sets and kits that contain multiple cosmetics and personal care products
  - Hotel amenities
  - Cosmetic and personal care products that are supplied as multi-packs
  - Cosmetic and personal care products that come in ampule and vials (should contain the following

instructions in Arabic and English):

- For external use only

- Avoid contact with eyes
- Open with caution

## 6. PACKAGING

1. The packaging of cosmetics and personal care products shall be designed so that, under conditions specified by the manufacturer for storage, transport and handling, it protects against damage and deterioration and does not adversely affect the product.
2. Metal aerosol dispensers used for packing cosmetics and personal care products shall comply with GSO 917 "Metal Aerosol Dispensers."

## 7. CONCLUSION

The GCC Standardization Organization has released GSO 1943: 2015, which defines product descriptions, safety requirements, labelling and product claims, as well as packaging and acceptance and rejection restrictions. Regulation is in line with EU restrictions on prohibited substances. The GCC Standardization Organization, a comparable agency, can develop standards that apply to everybody. The cosmetics definition is a verbatim copy of the EU beautifying product definition. The GCC Standardization Organization, a federation of GCC countries, has the ability to develop global operational standards (GSO). But it has its own laws for tactics, ingredients, labelling, and claims. The legislation is organized in the same way as the EU Regulation when it comes to restricted and prohibited substances. Annex II lists the prohibited substances, Annex III lists the restricted substances and Annexes IV to VI list the allowed colourants, preservatives and UV filters—the list of such ingredients is also very similar to that of the EU. In terms of labelling requirements, it is important to note that the graphics, images and phrases on the labels should be consistent with Islamic traditions and social values, that certain parts of the label have to be translated into Arabic and that claims have to be truthful (the legislation on claims follows the EU common claims criteria). Despite having the same basic legislation across all of the GCC member countries, each country requires a separate product notification (Bahrain does not require any notification) and the customs clearance process requirements may differ from country to country.

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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